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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/511,824	02/24/00	YAMAD Y	FUJ2-AZ72a

HM12/1024

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EXAMINER	
GABEL,G	
ART UNIT	PAPER NUMBER
1641	12

DATE MAILED: 10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/511,824	YAMAO ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,11-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicants' amendment and arguments filed 8/10/01 in Paper No. 12 is acknowledged and has been entered. Claim 9 has been amended. Applicant's submission of a Terminal Disclaimer is also acknowledged. Currently, claims 8-9 and 11-12 are pending and under examination.

Rejections Withdrawn

2. In light of Applicant's submission of a Terminal Disclaimer, the rejection of claims 8-9 and 11-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of prior U.S. Patent No. 6,030,845 is, hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9 and 11-12 stand rejected under 35 U.S.C. 112, second paragraph, for reason of record.

Claim 9, as amended, remains indefinite because it is unclear why "adding a hemolysis reagent" and "hemolysing the whole blood sample" appear to be recited as separate method steps as if further method steps are intended by Applicant.

Specifically, claim 9 fails to distinctly and consistently relate the steps of "adding" elements with their intended use. The following language is suggested but not required to assist Applicant in overcoming indefiniteness issues.

In claim 9, lines 4-10,

"adding a hemolysis reagent to the sample of the whole blood to hemolyse the blood corpuscles;

adding a latex reagent directly to the hemolyzed whole blood sample to react the hemolyzed sample in an agglutination reaction to form a reaction product ... reacts with an antibody immobilized onto an insoluble carrier of the latex reagent to provide a reaction product;"

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (US 4,889,815) in view of Minoru et al. (JP 07-035752) and in further view of Hasegawa et al. (JP 06-265554).

Bradwell et al. disclose an immunoassay system comprising a means for lysing whole blood with a hemolysis reagent (cuvette made of transparent suitable material charged with lysing reagent such as saponin/KCN). The system further comprises a means for reacting antigens in the whole blood sample to form a reaction mixture comprising insoluble carriers with antibodies immobilized thereto (latex bound antibodies) (see column 3, lines 16-33). The system further includes a nephelometer for use in analysing the reactions in whole blood without the need to remove blood cells or hemoglobin (see column 1, lines 51-54). A second detector is included to compensate for the amount of light absorbed possibly by the hemoglobin in the sample to minimize and correct for any degree of absorption by the hemoglobin in the sample (see column 1, lines 21-25, 51-54; column 3, lines 16-54 ; column 4, lines 59-61). In the system, wavelength is read where the strength of radiation scattered by antigen/antibody complex is high and the absorption by hemoglobin and other proteins is low.

Bradwell et al. differ in failing to irradiate and measure the reaction product at a wavelength range that is substantially free from absorption by both hemolysis and hemolysis reagent, i.e. 800 nm.

Minoru et al. disclose a system for performing selective immunological agglutination assay in a hemolyzed whole blood sample wherein antigenic substance immobilized onto insoluble carrier is mixed with the hemolyzed sample then HbA1C monoclonal antibody is added into the sample to form an agglutination reaction product (latex suspension). Absorbance of the reaction product is measured by a spectrophotometer (see entire Abstract).

Bradwell et al. and Minoru et al. differ in failing to disclose a detection system which [automatically] corrects for hematocrit.

Hasegawa et al. disclose an automated system for analyzing biochemical components such as whole blood samples in cuvettes. The system has the capability to optimize measurement of the sample by being able to decide as to the type of specimen that is being measured, i.e. whole blood; the system adjusts parameters so as to be applicable to whole blood. In case of immeasurable items, instructions are provided in the system to allow adjustment of parameters for further measurement of the blood in an optical measuring section, i.e. spectrophotometric measurement where results are subjected to hematocrit correction (see entire Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have determined the quantity of antigen in the method of Bradwell using a means such as a spectrophotometer as taught by Minoru for irradiating and measuring at any wavelength, including those free from absorption of hemolysis and hemolysis reagent, i.e. 800 nm, such as suggested by Bradwell, because spectrophotometers inherently have the capability to make measurements including

those at or near infrared levels. One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in having adjusted the spectrophotometer of the system to read at a wavelength of 800 nm because spectrophotometers are known to measure absorbance at such frequencies. Further it would have been obvious to one of ordinary skill in the art at the time of the instant invention to mathematically correct for hemoglobin content in the systems taught by Bradwell and Minoru by automatically subjecting the sample to hematocrit correction such as disclosed in the system of Hasegawa since calculations involving correction factors to arrive at a true mathematical value, i.e. concentration, are well within ordinary skill and conventional in current automated systems.

5. Claims 9 and 11-12 are currently free of prior art.

6. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7/16/01 prompted the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays at 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

10/18/01

Gailene R. Gabel
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
10/22/01